

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0443032	(X3) Date Survey Completed 05/31/2023
Name of Provider or Supplier Liberty Clinic, The	Street Address, City, State 2609 Glenn Hendren Dr, Liberty, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The New Liberty Hospital Clinic Laboratory was found to be in substantial compliance with 2 CFR Part 493, Requirements for Laboratories as a result of an offsite revisit survey July 10, 2023.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing (PT) records for 2022 and interview with the technical consultant(TC) #1, the laboratory failed to maintain a copy of all instrumentation data printouts for one of three PT events in 2022. Findings: 1. Review of 2022 PT records showed no instrument data printouts for 2022 Hematology/Coagulation third event. 2. Interview with the TC #1 on May 31, 2023 at 2:00 PM confirmed the laboratory failed maintain a copy of all instrumentation data printouts for one of three PT events in 2022.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of calibration records for Medonic hematology analyzer, policies and interview with the technical consultant(TC) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Medonic hematology analyzer calibration records for 2021, 2022, and to date May 31, 2023 showed calibration dates of February 2021, October 2021, January 2022, August 2022 and February 2023. 2. Review of the ploicy, "Quality Management For Moderate Complex Clinic Laboratories" states recalibration is to be done "every six months if not otherwise indicated." 3. Review of the calibration dates showed there were dates that exceeded 6 months from February 2021 to October 2021 and January 2022 to August 2022 for the following Medonic hematology analytes: white blood cell count, red blood cell count, hemoglobin, hematocrit, and platelet counts. 4. Interview with TC #1 on May 31, 2023 at 2:00 PM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range on the Medonic hematology analyzer.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the 2021/2022/2023 proficiency testing (PT) records and interview with technical consultant (TC) #1, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the 2022 Hematology/Coagulation- second event showed the laboratory obtained a "not graded" result for Vaginal Wet Preparation sample VA-02. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results to identify any problems that may require corrective action. 2. Interview with TC #1 on May 31, 2023 at 2:00 PM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of "Quality Management for Moderate Complexity Clinic Laboratories" policy, review of training records and interview with the technical consultant #1 (TC), the laboratory failed to perform semiannual competencies at six months for two of two testing personnel (TP) in 2022. Findings: 1. Review of : "Quality Management for Moderate Complexity Clinic Laboratories" policy states "Competency is assessed initially, at six months and annually thereafter for non-waived tests." 2. Review of 2022 training records showed the laboratory failed to perform semiannual competencies on TP #1 and TP #4 at six months. 3. Interview with TC #1 on May 31, 2023 at 2:00 PM confirmed the TC failed to perform semiannual competency at six months for two testing personnel in 2022.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of performance evaluations and interview with technical consultant (TC) #1, the TC failed to evaluate and document annual performance evaluations for two of seven testing personnel (TP) in 2022. Findings: 1. Review of performance evaluations showed no annual performance evaluation for testing personnel #1 and #3 in 2022 for the following: TP #1 - no annual competency for CBC TP #3 - no annual competency for CBC and Micro Urine/Wet Prep 2. Interview with TC #1 on May 31, 2023 at 2:00 PM confirmed the TC failed to evaluate and document annual performance evaluation for TP #1 and #3 in 2022.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of personnel records, and interview with the technical consultant (TC) #1, the laboratory failed to provide academic qualifications required to perform moderate complexity testing for one of seven testing personnel. (Refer to D6065)

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of academic credentials and interview with the technical consultant (TC) #1, the laboratory failed to provide academic credentials to qualify one of seven testing personnel (TP). Findings: 1. The laboratory failed provide academic credentials to show TP #2 was qualified to perform moderate complexity testing. 2. Interview with the technical consultant (TC) #1 on May 31, 2023 at 2:00 PM confirmed the laboratory failed to provide academic credentials for TP #2.